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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,941	08/24/2001	Robin Thurmond	ORT-1489	2660

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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,941	THURMOND ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 6/30/04 is acknowledged and has been entered. Claim 1 has been cancelled. Claims 2-3 have been amended. Accordingly, claims 2-3 are pending and are under examination.

Rejections Moot

2. The rejections of claim 1 are now moot in light of Applicant's cancellation of the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite in lacking a correlation step which relates the presence of p10Ii fragment of invariant chain (Ii) in a subject's blood sample and the [monitored] effect of in vivo administration of a cathepsin S inhibitor to the subject, as required by the preamble. Does Applicant intend that the presence of p10Ii fragment of invariant chain (Ii) in a subject's blood sample positively identifies that a cathepsin S

inhibitor has been administered to the subject in vivo; hence, causing inhibition of cathepsin S. Please clarify.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 2-4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman et al. (WO 99/58153) in view of Willman et al. (US Patent 6,495,333) for reason of record in Office Action mailed 3/25/04.

Response to Arguments

5. Applicant's arguments filed 6/30/04 have been fully considered but they are not persuasive.

A) Applicant argues that the combination of Chapman et al. with Willman et al. does not render obvious the claimed invention and that there would have been no motivation to select various aspects of their teachings for combination to arrive at the teaching of the claimed invention. Applicant points to pages 13-14, Example III, and claims 35-51 and contends that the methods described by Chapman for monitoring the effects of cathepsin S inhibitors, detect the presence or absence of Ii chain, not the presence of p10Ii fragment, and on a cell surface, not from a blood sample. Applicant also argues that the 103 rejection was made in hindsight by the Examiner since it fails to explain why the person of ordinary skill in the art would have looked to the references cited. Applicant then concludes that a prima facie case of obviousness has not been established and that the rejection was made in error

In response, claim 2 recites the "comprising" language and does not appear to exclude the teaching of Chapman. Chapman teaches monitoring the effects of cathepsin S activity on Ii degradation in Example III wherein the Ii chain found present after cathepsin S inhibition, was identified and confirmed to be a 10 kDa fragment of Ii; hence, P10Ii.

In response to applicant's arguments against the Chapman reference individually regarding detection of Ii chain on "cell surface" of splenocytes, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA

1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the rejection is based on the combined teaching of Chapman with Willman. Chapman discloses monitoring the effect of in vivo administration of cathepsin S inhibitor in a subject. Chapman shows that by detecting the presence of invariant chain on the surface of dendritic cells or antigen presenting cells, using labeled Ii-specific antibody, the effect of in vivo cathepsin S inhibitor to inhibit cathepsin S activity can be monitored. Chapman teaches obtaining a cell sample of splenocytes, lysing the cells, then analyzing the lysates for the presence or accumulation of intermediate degradation product of Ii. The Ii chain was subsequently identified as having a 10 kDa fragment, i.e. p10Ii fragment. Willman is incorporated into the teaching of Chapman for the teaching that dendritic cells or antigen presenting cells, from which invariant chains are contained, are present in peripheral blood samples.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use peripheral blood samples taught in the method of Willman, to detect the presence of intermediate degradation product of Ii, i.e. p10Ii, as

taught by Chapman, because Willman provided that there is difficulty in studying subcellular function in dendritic cells because of their rarity, but showed that ease in collection of blood as opposed to lymphatic tissue, achieves the goal of non-invasive procedures in monitoring compound activity for pharmaceutical evaluation studies of autoimmune disorders such as in the method of Chapman.

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571)

272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 5:30 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
September 16, 2004
GG

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
9/17/04